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PATENT  
Attorney Docket No. 38730.830029.001  
Express Mail Label No. EL222668295US

IN THE U.S. PATENT AND TRADEMARK OFFICE  
PATENT APPLICATION TRANSMITTAL

Box PATENT APPLICATION  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

This is a request for filing a X Utility        Design Patent Application under  
37 CFR §1.53(b). This application, entitled SUBSTANCE DELIVERY APPARATUS  
is:        an Original

X a Continuation

       a Divisional

       a Continuation-in-Part

Patent Application of pending prior application Serial No. 08/989,150 filed on December 12, 1997  
by Michael CALLUAUD and Victor YERBURY for SUBSTANCE DELIVERY APPARATUS which  
is a U.S. Application of prior Australian application Serial No. PO4186 filed on December 12,  
1996, from which priority is claimed.

Enclosed are:

       An original specification, claims, drawing and Declaration and Power of Attorney.

X A true copy of the prior application, including the specification, claims, drawings, oath/  
declaration:

14 pages of specification

6 pages of claims

1 pages of abstract

7 pages of drawings

3 pages of Declaration

X A preliminary amendment is enclosed to be entered in the new application after a filing  
date has been granted.

       New formal drawings are enclosed.

       A List of References.

The filing fee is calculated below:

	(Col. 1)	(Col. 2)
FOR:	NO. FILED	NO. EXTRA
BASIC FEE		
TOTAL CLAIMS	49- 20 =	* 29
INDEP CLAIMS	2 - 3 =	* 0
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENTED		

\*If the difference in Col. 1 is less than zero, enter  
"0" in Col. 2.

SMALL ENTITY

RATE	FEE
	\$380
x 9 =	\$
x38 =	\$
x130 =	\$
TOTAL	\$

OR  
OR  
OR  
OR  
OR

OTHER THAN A  
SMALL ENTITY

RATE	FEE
	\$ 760
x18 =	\$ 522
x78 =	\$
+260 =	\$
TOTAL	\$ 1282

X A check in the amount of \$1282.00 is enclosed.

\_\_\_\_ Please charge Deposit Account No. 08-2623 in the amount of \$\_\_\_\_\_.

\_\_\_\_ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 08-2623.

X The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 08-2623. A duplicate copy of this sheet is attached.

X Any filing fees under 37 CFR 1.16 for the presentation of extra claims.

X Any patent application processing fees under 37 CFR 1.17.

\_\_\_\_ Cancel claims \_\_\_\_\_.

\_\_\_\_ Priority under 35 U.S.C. 119 is claimed on the basis of prior Australian application Serial No. PO4186, filed on December 12, 1996. A certified copy of this prior application was previously filed in the parent application.

X Amend the specification by inserting before the first line the sentence:

--This is a continuation of co-pending application Serial No. 08/989,150, filed on December 12, 1997, which is hereby incorporated by reference in its entirety.--

X The prior application is assigned to ResMed Limited, an Australian company.

X The power of attorney in the prior application is to:

Andrew D. Sorensen, Reg. No. 33,606, William J. Kubida, Reg. No. 29,664, F.A. "Sandy" Sirr, Reg. No. 17,265, Earl C. Hancock, Reg. No. 19,472, Homer L. Knearl, Reg. No. 21,197, Gregg I. Anderson, Reg. No. 28,828, Carol W. Burton, Reg. No. 35,465, Richard A. Bachand, Reg. No. 25,107, William W. Cochran, Reg. No. 26,652, Lee R. Osman, Reg. No. 38,260, John R. Wahl, Reg. No. 33,044, Stuart T. Langley, Reg. No. 33,940, and James A. Pinto, Reg. No. 40,774.

a. X The power appears in the original papers of the prior application.

b. \_\_\_\_\_ Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.

c. \_\_\_\_\_ Recognize as associate attorney and address all future communications to:

Lee R. Osman  
Holland & Hart LLP  
555 17<sup>th</sup> Street, Suite 3200  
P.O. Box 8749  
Denver, CO 80201-8749

\_\_\_\_ A verified statement that this filing is by a small entity:

\_\_\_\_ is attached.

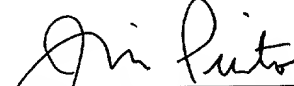
\_\_\_\_ has been filed in the parent application and such status has been re-determined and is still proper and desired. (37 C.F.R. 1.28(a)).

Please forward all correspondence to:

Lee R. Osman, Reg. No. 38,260  
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Phone: (303) 295-8589  
Fax: (303) 295-8261

Dated this 20<sup>th</sup> day of December, 1999.

Respectfully submitted,



James A. Pinto, Reg. No. 40,774  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Continuation Application of:

Michel CALLUAUD and Victor YERBURY

Serial No.

Filed: Herewith on December 20, 1999

For: SUBSTANCE DELIVERY APPARATUS

Examiner:

Art Unit: 3761

CERTIFICATE OF MAILING BY EXPRESS MAIL

Box PATENT APPLICATION

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The undersigned hereby certifies that the attached:

1. Patent Application Transmittal;
2. Preliminary Amendment;
3. Copy of prior application (which includes 14 pages of description, 6 pages of claims, 7 sheets of drawings, 3 pages of Declarations, and 1 page of abstract),
4. Check in the Amount of \$1,282.00;
5. Return Card; and

this Certificate of Mailing by Express Mail relating to the above application, were deposited as "Express Mail," Mailing Label No. EL222668295US, with the U.S. Postal Service, addressed to Box Patent Application, Assistant Commissioner for Patents, Washington, D.C., 20231, on this 20<sup>th</sup> day of December, 1999.

December 20, 1999

Valerie H. Brown  
Mailer

December 20, 1999

James A. Pinto  
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PATENT  
Attorney Docket No. 38730.830029.001  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Continuation Application of:

Michel CALLUAUD and Victor YERBURY

Serial No.

Filed: Herewith on December 20, 1999

For: SUBSTANCE DELIVERY APPARATUS

Examiner:

Art Unit: 3761

PRELIMINARY AMENDMENT

Box PATENT APPLICATION  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

This Preliminary Amendment is filed concurrently with a continuation application.

In the Specification:

At page 1, after the title, insert --This is a continuation of co-pending application Serial No. 08/989,150, filed on December 12, 1997, which is hereby incorporated by reference in its entirety.--

REMARKS

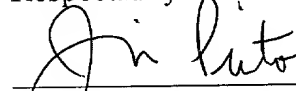
This continuation application is a continuation of Serial No. 08/989,150. Claims 1-26 and 27-49 are pending, with claims 1 and 27 being independent claims.

The proper filing fee is believed enclosed with this continuation application, however, should an additional fee be required please charge Deposit

Account 08-2623. Should any extensions of time be required, consider this a petition thereof and charge Deposit Account 08-2623 the required fee.

Signed at Denver, Colorado, this 20<sup>th</sup> day of December, 1999.

Respectfully submitted,



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## A SUBSTANCE DELIVERY APPARATUS

### FIELD OF THE INVENTION

The present invention relates to a substance delivery apparatus for use with a system for supplying breathable gas to a human or animal.

### 5 BACKGROUND OF THE INVENTION

Treatment of Obstructive Sleep Apnea (OSA) with Continuous Positive Airway Pressure (CPAP) flow generator systems involves the continuous delivery of a breathable gas (generally air) pressurised above atmospheric pressure to a patient's airways via a conduit and a mask. CPAP pressures of 4cm H<sub>2</sub>O to 22cm H<sub>2</sub>O are  
10 typically used for treatment of OSA, depending on patient requirements. Treatment pressures for assisted ventilation can range of up to 32cm H<sub>2</sub>O and beyond, again depending on patient requirements.

For either the treatment of OSA or the application of assisted ventilation or similar, the pressure of the gas delivered to patients can be constant level, bi-level (in  
15 synchronism with patient inspiration) or auto setting in level. Throughout the specification reference to CPAP is intended to incorporate a reference to any one of, or combinations of, these forms of pressurised gas supply.

It is difficult to administer substances such as medicines to patients undergoing CPAP treatment without interrupting the treatment by removing the gas supply mask.

20 It is an object of the present invention to ameliorate the above disadvantage.

### SUMMARY OF THE INVENTION

In a first aspect, the present invention provides a substance delivery apparatus for use with a system for supplying breathable gas to a human or animal, the apparatus including:

- 25 means to measure the pressure of the supplied breathable gas;
- means to detect inhalation by the human or animal; and
- means to deliver the substance to the human or animal during inhalation at a pressure higher than the supplied pressure of the breathable gas.

In a second aspect the invention provides a method of delivering a substance to a human or animal being supplied with breathable gas, the method includes the steps of:

measuring the pressure of the supplied breathable gas;

detecting inhalation by the human or animal; and

5 delivering the substance to the human or animal during inhalation at a pressure higher than the supplied pressure of the breathable gas.

The substance is preferably a medicinal substance and, desirably, in the form of a gas, mist, aerated suspension, jet, spray, gas mixture or the like.

The substance is preferably delivered to the respiratory system of the human or  
10 animal and, in particular, to the nasal airways.

The supplied breathable gas is preferably pressurised above atmospheric pressure.

The system for supplying the breathable gas preferably includes a pressurized gas flow generator in fluid communication with a mask worn by the human or animal  
15 via a flexible conduit, and the inhalation detection means includes an airflow sensor adapted to measure the volumetric flow rate of the breathable gas passing through the conduit and generate a first input signal indicative of the breathable gas flow rate. The term mask is herein understood to include facemasks, nose masks, mouth masks, appenditures in the vicinity of any of these masks and the like.

20 The first signal is preferably amplified by a first amplifier into a second input signal also indicative of the gas flow rate. A derivative of the first signal is also generated by a differentiating filter to determine the acceleration or deceleration of the gas, which is indicative of inhalation or exhalation respectively, and is represented by a third input signal.

25 When the airflow sensor is disposed downstream of the mask's vent to atmosphere then inhalation can be detected by sensing a reversal of the direction of the gas flow through the vent. Inhalation can also be detected by sensing an interruption of the gas flow.

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The apparatus preferably also includes means to measure the volume of the substance to be delivered to the human or animal.

The pressure measuring means is preferably a pressure transducer connected to the conduit which is adapted to generate a fourth input signal indicative of the pressure of the gas in the conduit. The fourth input signal is preferably amplified by a second amplifier into a fifth input signal also indicative of the gas pressure.

The substance delivery means is preferably a positive displacement pump, most preferably a diaphragm pump. The diaphragm pump is desirably in fluid communication with a substance reservoir via a one-way valve adapted to allow the substance to only pass from the reservoir to the pump. The pump is preferably also in fluid communication with the gas supply conduit via a one-way valve adapted to allow the substance to only pass from the pump to the conduit.

The diaphragm of the pump is desirably displaced by a linear drive means which, in one form, may take the form of an electromagnet. In other forms, a rotary drive means such as an electric DC motor, an electric AC motor, a stepper motor, or a brushless motor are used with a rotary to linear converter interposed between the rotary drive means and the diaphragm pump.

The apparatus preferably also includes a first control system adapted to receive the second, third and fourth input signals. The control system preferably also includes input means adapted to allow the input of a predetermined sixth input indicative of the volume of the substance to be delivered and a predetermined seventh input signal indicative of the amount by which the pressure of the delivered substance should exceed the pressure of the supplied breathable gas. The first control system is preferably adapted to receive the second, third, fifth, sixth and seventh input signals to calculate and generate a first output signal indicative of the amount of displacement of the linear or rotary drive means and a second output signal indicative of the direction of the displacement required to produce negative or positive pumping pressure.

The first and second output signals are preferably sent to a second control system which converts them into third and fourth output signals indicative of drive

means displacement and direction respectively, the third and fourth output signals being compatible with the linear or rotary drive means.

Preferably, the first and second output signals are sent to a second control system adapted to convert them into third and fourth output signals indicative of drive  
5 means displacement and direction respectively, the third and fourth output signals being compatible with the linear or rotary drive means.

The input and output signals can be analog, digital or the like.

The described embodiments have been developed primarily for use in delivering medicinal substances to patients using Continuous Positive Airway Pressure  
10 (CPAP) gas delivery systems in, for example, the treatment of Obstructive Sleep Apnea (OSA) or similar sleep disorder breathing conditions.

The invention will be described hereinafter with reference to these applications. However, it will be appreciated that the invention is not limited to this particular field of use. As examples, the invention may also be used in conjunction  
15 with suitable mask and gas delivery systems for other treatments such as assisted ventilation, assisted respiration or mechanical ventilation.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention will now be described, by way of example only, with reference to the accompanying figures in which:

20 Figure 1 is a schematic diagram of a substance delivery apparatus according to a first embodiment of the invention;

Figure 2 is a schematic diagram of a substance delivery apparatus according to a second embodiment of the invention;

Figure 3 is a schematic diagram of a substance delivery apparatus according to  
25 a third embodiment of the invention;

Figure 4 is a schematic diagram of the apparatus of Figure 3 during inhalation;

Figure 5 is a schematic diagram of the apparatus shown in Figure 3 during exhalation;

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Figure 6 is a partial schematic diagram of a substance delivery apparatus according to a fourth embodiment of the invention; and

Figures 7a, 7b and 7c are partial schematic diagrams of a substance delivery apparatus according to a fifth embodiment of the invention.

## 5 DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring firstly to Figure 1, there is shown a first embodiment of a substance delivery apparatus 10 according to the invention. The apparatus 10 is used with a system, indicated generally at 12, for supplying air, indicated by arrow 14, to a human patient (not shown). The system 12 includes a pressurised gas flow generator 16 in  
10 fluid communication with a mask 18 via conduit 20.

The apparatus 10 includes a means to measure the pressure of the air 14 and to detect patient inhalation, in the form of an air flow sensor 22. The sensor 22 is interposed in the conduit 20 between the mask 18 and the pressurised gas flow generator 16. The airflow sensor 22, in the form of a fixed orifice, is connected to an  
15 electronic flow transducer 24. A variable orifice, venturi tube, Pitot tube or tubes bundle can also be used to sense airflow. The transducer 24 generates a first electrical input signal 26 indicative of the flow rate of the air 14 passing through the conduit 20 which is sent to a first flow signal processing amplifier and differentiating filter 28 which in turn generates second and third input signals 30 and 32 respectively.

20 The second input signal 30 is an amplified version of the first input signal 26. The third input signal 32 is the derivative of the first signal 26, with acceleration and deceleration being respectively indicative of inhalation or exhalation. When a patient inhales they apply suction to the air being delivered thus causing acceleration. Upon exhalation the air being delivered is obstructed by the exhaled air flowing in the  
25 opposite direction thus causing deceleration.

An air pressure transducer 34 is also connected to the conduit 20 and generates a fourth electrical input signal 36 indicative of the pressure in the conduit. The fourth signal 36 is delivered to an air pressure processing amplifier 38 which generates a fifth input signal 40 also indicative of the pressure in the conduit 20.

The second, third and fifth input signals 30, 32 and 40 are fed to a first control system 42. The first control system 42 also receives sixth and seventh predetermined input signals 44 and 46 from manual inputs 48 and 50 in the form of potentiometers accessible by a system operator. Variable resistors can also be used as the manual  
5 inputs. The sixth input signal 44 is indicative of the volume of substance to be delivered to the mask during each inhalation cycle of the patient. The seventh signal 46 is indicative of the amount by which the delivery pressure of the substance is to exceed the measured pressure of the air 14 in the conduit 20.

The means to deliver a substance 52 to the mask 18 includes a substance  
10 reservoir 54 connected by conduit 56 to diaphragm pump 58 having a flexible diaphragm 60. A one way valve 62 is interposed between the reservoir 54 and pump 58 and permits the substance 52 to only enter the pump 58. The pump 58 is in fluid communication with the conduit 20 by virtue of conduit branch 64 and one way valve 66 which allows the substance 52 to pass from the pump 58 to the conduit 20.

15 The stroke of the diaphragm 60 is controlled by an electromagnet drive means 68, in the form of a magnet 70 connected to the centre of the diaphragm 60 and surrounded by electrical windings 72. The drive means 68 are controlled by a second control system 74.

In response to receiving the second, third, fifth, sixth and seventh input  
20 signals, the first control system 42 generates first and second output signals 76 and 78, respectively indicative of the electromagnet displacement magnitude and direction. Displacement in the direction of arrow 80 draws the substance 52 into the pump 58. Displacement in the direction of arrow 82 causes the substance 52 to be pumped into the conduit branch 64 and thereafter the conduit 20. The output signals 76 and 78 are  
25 received by the second control system 74 which issues third and fourth output signals 84 and 86 respectively, which are compatible with the drive means 68. The third output signal 84 is indicative of the amount of displacement of the electromagnet 68 and the fourth signal 86 is indicative of the displacement direction.

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In use, when the system is switched on, breathable air 14 is supplied by the gas flow generator 16 to the mask 18 via the conduit 20 so the patient may breathe.

As the patient inhales, an analogue to digital converter (not shown) in the control system 42 samples the air flow information of the first input signal 30 over a few breaths and stores it in a memory (not shown). The stored values are integrated with respect to the time of the inhalation portion of their respective breathing cycle. The integrated value is the tidal volume of each breath and is also stored in the memory. The stored values of the tidal volume are averaged over a small number of breaths to provide an average value of the tidal volume.

From the average value of the tidal volume and the setting of the manual input 48 the volume of the substance 52 (ie, the drug or gas) to be delivered for each breath is calculated. The control system 42 also calculates the magnitude of the current to be applied to the windings 72 of the diaphragm pump 58.

When the third input signal 32 indicates exhalation, the control systems 42 and 74 calculate and issue the third and fourth output signals 84 and 86 to the windings 72. The direction of the current applied to the windings 72 causes the magnet 70 and the diaphragm 60 to be displaced in the direction of the arrow 80 to the position shown by phantom line 87. This movement of the diaphragm 60 draws the substance 52 past the one way valve 63 and into the pump 58. The magnitude of the current applied to windings 72 is proportional to the displacement of the diaphragm 60 and also therefore the volume of gas drawn into the pump 58 which is delivered to the patient during the next inhalation cycle. At the end of the patient exhalation cycle the current applied to the windings 72 remains constant and the magnet 70 and diaphragm 60 remain as indicated by line 87.

When the third input signal 32 indicates inhalation, the control systems 42 and 74 reverse the current flowing into the windings 72, thereby displacing the magnet 70 and the diaphragm 60 in the direction indicated by the arrow 82 to the position shown by phantom line 89. This movement forces the substance 52 from the pump 58 through the one way valve 68 and conduit branch 64 into the mask 18.

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The air pressure of the gas 14 in the conduit 20 is exceeded by the pressure of the substance pumped through conduit branch 64. The supply pressure of the substance 52 is calculated by the control system 42 and is the sum of the pressure measured by pressure transducer 34 in conduit 20 and the pressure increment set by manual input 48.

5 The substance 52 is then delivered to the patient via the conduit 64 and the mask 18.

A second embodiment of the present invention is shown in Figure 2, in which like reference numerals are used to indicate like features.

The first control system 42 of the second embodiment incorporates a microcontroller 92 and a linear position transducer 94 connected to the magnet 70 to  
10 provide a feedback signal 96 indicative of the position of the magnet 70 and the diaphragm 60, to which it is connected.

The two manual inputs 48 and 50 are replaced by a digital control panel 98 with: a three digit digital display 100; three push buttons: Mode 102, "+" 104, "-" 106; and three LEDs to indicate the mode selected: Volume 108, Delivery Pressure  
15 110 and Run 112.

The operation of this system is generally similar to the description above except where indicated below.

Successive depression of the Mode push button 102 cycles through the three modes of operation: Volume, Delivery Pressure and Run.

20 When Volume or Delivery Pressure is selected, the digital display 100 indicates the current setting of that parameter. This value may be modified if required by operating either of the two push buttons "+" 104 or "-" 106.

When Run is selected, the parameters stored in the memory of the microcontroller 90 calculate the desired position of the magnet 70. This is then  
25 compared with the actual magnet position indicated by the linear position transducer 94. Any difference produces an error signal that is used to correct the position of the magnet 70 to the desired position.

A third embodiment of the present invention is shown in Figures 3 to 5, in which like reference numerals are again used to indicate like features. In this

embodiment, the flow processing amplifier and differentiating filter 28 again detects the onset of inhalation by sensing a change in the rate of flow (ie. the acceleration or deceleration) of the gas flowing past the sensor 22.

The output signal 120 from the amplifier filter 28 of this embodiment is active  
5 when the onset of inhalation is detected and remains active for the duration of the inhalation portion of the breathing cycle. The output signal 120 from the amplifier filter 28 is not active for the exhalation portion of the breathing cycle.

The output signal 120 is supplied to a driver stage 122 and an inverter stage 124.

10 When the output signal 120 is active, during inhalation, the driver stage 122 is active and applies power to an electromagnetic winding 126 through a connection 128. When the output signal 120 is inactive, during exhalation, the inverter stage 124 supplies a drive signal 130 to a driver stage 132. The driver stage 132 is activated and supplies power to an electromagnetic winding 134 through a connection 136.

15 A magnetic core 138 is located within the electromagnetic winding 126. Similarly, a magnetic core 140 is located within the electromagnetic winding 134.

The magnetic core 138 and the magnetic core 140 are connected by a connecting rod 142 which is also connected to a sliding spool valve 144.

20 When the winding 126 is energised through the connection 128 the magnetic core 138 is displaced in the direction of arrow 150 and pulls with it the spool valve 144 and core 140.

When winding 134 is energised through connection 136 the magnetic core 140 is displaced in the direction of arrow 152 and pulls with it the spool valve 144 and core 138.

25 The body 154 of the spool valve 144 is connected to the gas flow generator 16 through a branch conduit 156 connected to the conduit 20.

A diaphragm motor 157 is comprised of housing halves 158 and 160 separated by a diaphragm 162 which defines cavities 164 and 166. A diaphragm pump 168 is comprised of housing halves 170 and 172 separated by a diaphragm 174 which defines

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cavities 176 and 178. The cavity 164 is connected to the spool valve body 154 by a conduit 182. The cavity 166 is connected to the spool valve body 154 by a conduit 184. The cavity 176 is open to atmosphere. The cavity 178 is connected to the source 54 of the substance 52 to be delivered by the conduit 56 and the one-way valve 62.  
s The cavity 178 is also connected to the mask 18 by the conduit 64 and the one-way valve 66.

The motor diaphragm 162 and the pump diaphragm 174 are connected by a connecting rod 186. The connecting rod 186 passes through an air sealed bearing (not shown) between cavities 166 and 176.

10 An adjusting screw 188 is located on the top of housing halve 158.

With reference to Figure 4, the operation of the apparatus will be described during the inhalation portion of the breathing cycle.

As the patient start to inhale, the second output signal 120 from the flow processing amplifier 28 is set to active and activates the driver stage 122. The inverter stage 124 is inactive and magnetic core 140 is free to move. The driver stage 122  
15 supplies power to the electromagnetic winding 126 through connection 128. The magnetic core 138 is forced in the direction of the arrow 150 and with it the spool valve 144. The air 14 now flows from the branch conduit 156 into the spool valve body 154 and is diverted by the spool valve 144 through the conduit 182 and into the cavity 164.  
20 The pressure of the air entering the cavity 164 forces the motor diaphragm 162 in the direction of arrow 190 and with it the pump diaphragm 174. The cavity 178 is already filled with the substance 52 to be delivered to the mask 18.

The displacement of the pump diaphragm 174 into the cavity 178 increases the substance pressure, closes the one-way valve 62, opens the one-way valve 66, and  
25 forces the substance 52 into the conduit 64. The conduit 64 is in fluid communication with the conduit 20 and the mask 18 and the substance 52 is thereby delivered to the mask 18 and the patient.

With reference to Figure 5, the operation of the apparatus will be described during the exhalation portion of the breathing cycle.



As the patient start to exhale, the second output signal 120 from the flow processing amplifier 28 is set to inactive. The driver stage 122 is not activated and power is not supplied to the electromagnetic winding 126 through connection 128. The magnetic core 138 is therefore free to move. As the output signal 120 from the flow processing amplifier 28 is now inactive, the inverter stage 124 turns its output signal 130 to active and activates the driver stage 132. The driver stage 132 supplies power to the electromagnetic winding 134 through the connection 136 and the magnetic core 140 is forced in the direction of the arrow 152 and with it the spool valve 144. The air flows from the branch conduit 156 into the spool valve body 154 and is diverted by the spool valve 144 through the conduit 184 into the cavity 166. The pressure of the air in the cavity 166 forces the motor diaphragm 162 in the direction of arrow 192 and with it the pump diaphragm 174. The displacement of pump diaphragm 174 into cavity 176 produces a vacuum in cavity 178, closes the one-way valve 66, opens the one-way valve 62, and draws the substance 52 through the conduit 56 into the cavity 178.

The movement of the motor diaphragm 162 and pump diaphragm 174 is limited by the adjusting screw 188. The setting of the screw 188 governs the maximum displacement of the motor diaphragm 162 and pump diaphragm 174 in direction of the arrow 192, therefore controlling the volume of the substance 52 able to be drawn into the cavity 178 for delivery to the patient during the next inhalation.

The pump diaphragm 174 is smaller in area than the motor diaphragm 162. Accordingly, a given pressure supplied to motor diaphragm 162 will produce a greater pressure from the pump diaphragm 174. Therefore, the pressure delivered by the pump diaphragm 174 into the conduit 64 and the patient mask 18 will always exceed the pressure of the gas in the conduit 20. The ratio between the pressure in the conduit 20 and the conduit 64 is proportional to the ratio between the area of the diaphragms 174 and 162.

In another embodiment (not shown) the motor diaphragm 157 is replaced by an electric motor, such as a stepper motor, controlled by a control system to provide more accurate delivery of the substance 52.

A fourth embodiment of the present invention is shown in Figure 6, in which like reference numerals are again used to indicate like features. This embodiment is for use in conjunction with a bi-level CPAP flow generator (not shown) that delivers breathable gas at a relatively high treatment pressure to the mask during patient inhalation and at a relatively low treatment pressure during exhalation. The applicant markets such a bi-level system under the trade mark VPAP.

This embodiment includes a motor cylinder 200 having a slidable piston 202 which defines cavities 204 and 206. A pump cylinder 208 is also provided having a slidable piston 210 which defines cavities 212 and 214. The pistons 202 and 210 are connected by a connecting rod 216 which passes through an air sealed bearing 218.

The cavity 204 is connected to the conduit 20 by the branch conduit 156. The cavities 206 and 212 are open to atmosphere. The cavity 214 is connected to the source 54 of the substance 52 by the conduit 56 via the one-way valve 62. The cavity 214 is also connected to the mask 18 by the conduit 64 and the one-way valve 66.

The pistons are biased in the direction of arrow 220 by a spring 222.

The operation of the apparatus shown in Figure 6 will now be described. During exhalation, relatively low pressure gas is passing through conduit 20 which generates only a small amount of force on the piston 202. The spring 222 overcomes this force and drives the pistons 202 and 210 in the direction of the arrow 220 thereby creating a vacuum in cavity 214. The vacuum draws the substance 52 past the one-way valve 62 and into the cavity 214.

During exhalation, relatively high pressure gas is passing through the conduit 20 which generates enough force on the piston 202 to overcome the spring 222 and drive the pistons 202 and 210 in the direction of arrow 224. This forces the substance in the cavity 214 past the one-way valve 66 and into the mask 18 via the conduit 64.

The surface area of the piston 202 is larger than that of the piston 210 and the pressure generated by the piston 210 will therefore exceed that applied to the piston 202. Accordingly, the substance delivery pressure will always exceed the pressure produced by the flow generator during the inhalation phase of the breathing cycle. The

ratio between the surface areas of the pistons 202 and 210 is proportional to the ratio between the breathable gas pressure and the substance delivery pressure.

A fifth embodiment of the present invention is shown in Figures 7a, 7b and 7c. The fifth embodiment is essentially a modification of the fourth embodiment so it will  
5 work with a constant pressure flow generator.

The fifth embodiment includes a control valve 230 interposed between the conduit 20 and the motor cylinder 200. The valve 230 includes an inlet 232 connected to the conduit 20, a first outlet 234 connected to the cavity 204 and a second outlet 236 open to atmosphere.

10 The valve 232 is controlled by an electronic valve controller 238 which receives a signal 240 indicative of inhalation or exhalation, as discussed with respect to earlier embodiments.

When the signal 240 indicates inhalation, the controller 238 causes the valve 230 to move to the position indicated in Figure 7b. In this position, the air 14 is  
15 diverted into the cavity 204 causing the pistons to move in the direction of the arrow 224 and the substance 52 to be pumped into the mask 18, as previously described..

When the signal 240 indicates exhalation, the controller 238 causes the valve 230 to move to the position shown in Figure 7c. In this position, the air in the cavity 204 is vented to atmosphere as the pistons move in the direction of the arrow 220 under  
20 the influence of the spring 222. As previously described, this movement also causes the substance 52 to be drawn into the cavity 214.

The present invention, at least in preferred forms, provides a measured substance dose to a human or animal during inspiration only, thereby greatly reducing drug wastage.

25 The preferred apparatus also allows the substance to be delivered to the patient without interrupting CPAP, or similar treatment, or sleep, thereby increasing patient comfort and convenience.

The preferred apparatus also obviates the need for a patient to remember to take medicine.

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The invention has been described with reference to specific examples. However, it will be appreciated by those skilled in the art that the invention may be embodied in many other forms.

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We claim:

1. A substance delivery apparatus for use with a system for supplying breathable gas to a human or animal, the apparatus including:

means to measure the pressure of the supplied breathable gas;

5 means to detect inhalation by the human or animal; and

means to deliver the substance to the human or animal during inhalation at a pressure higher than the supplied pressure of the breathable gas.

2. An apparatus as claimed in claim 1, wherein the substance is a medicinal substance.

10 3. An apparatus as claimed in claim 1, wherein the substance is in the form of a gas, mist, aerated suspension, jet, spray, gas mixture or the like.

4. An apparatus as claimed in claim 1, wherein the substance is delivered to the respiratory system of the human or animal.

15 5. An apparatus as claimed in claim 4, wherein the substance is delivered to the nasal airways of the human or animal.

6. An apparatus as claimed in claim 1, wherein the supplied breathable gas is pressurised above atmospheric pressure.

7. An apparatus as claimed in claim 1, wherein the system for supplying breathable gas includes a pressurized gas flow generator in fluid communication with a mask worn by the human or animal via a flexible conduit, and the inhalation detection means includes an airflow sensor adapted to measure the volumetric flow rate of the breathable gas passing through the conduit and generate a first input signal indicative of the breathable gas flow rate.

25 8. An apparatus as claimed in claim 7, further including a first amplifier to amplify the first input signal into a second input signal also indicative of the breathable gas flow rate.

9. An apparatus as claimed in claim 7, further including a differentiating filter to derive the first signal into a third input signal indicative of acceleration or

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deceleration of the breathable gas to thereby indicate inhalation or exhalation respectively.

10. An apparatus as claimed in claim 7, wherein the mask includes a gas washout vent to atmosphere and the airflow sensor is disposed downstream of the vent  
5 such that inhalation can be detected by sensing a reversal of the direction of the breathable gas flow through the vent.

11. An apparatus as claimed in claim 10, wherein inhalation is detected by sensing an interruption of the breathable gas flow through the vent.

12. An apparatus as claimed in claim 1, further including means to  
10 measure the volume of the substance to be delivered to the human or animal.

13. An apparatus as claimed in claim 1, wherein the pressure measuring means is a pressure transducer connected to the conduit, said transducer being adapted to generate a fourth input signal indicative of the pressure of the breathable gas in the conduit.

14. An apparatus as claimed in claim 13, including a second amplifier to  
15 amplify the fourth input signal into a fifth input signal also indicative of the breathable gas pressure.

15. An apparatus as claimed in claim 1, wherein the substance delivery means is a positive displacement pump.

20 16. An apparatus as claimed in claim 15, wherein the positive displacement pump is a diaphragm pump.

17. An apparatus as claimed in claim 16, wherein the diaphragm pump is in fluid communication with a substance reservoir via a one-way valve adapted to allow the substance to only pass from the reservoir to the diaphragm pump.

25 18. An apparatus as claimed in claim 16, wherein the diaphragm pump is in fluid communication with the gas supply conduit via a one-way valve adapted to allow the substance to only pass from the diaphragm pump to the conduit.

19. An apparatus as claimed in claim 16, wherein the diaphragm pump is displaced by a linear drive means.

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20. An apparatus as claimed in claim 19, wherein the linear drive means is an electromagnet.

21. An apparatus as claimed in claim 16, wherein the diaphragm of the diaphragm pump is displaced by a rotary to linear converter driven by a rotary drive  
5 means.

22. An apparatus as claimed in claim 21, wherein the rotary drive means is an electric DC motor, an electric AC motor, a stepper motor or a brushless motor.

23. An apparatus as claimed in claim 19, further including a first control system having input means adapted to allow the input of a predetermined sixth input  
10 signal indicative of the volume of the substance to be delivered and a predetermined seventh input signal indicative of the amount by which the pressure of the delivered substance should exceed the pressure of the supplied breathable gas, said first control system being adapted to receive the second, third, fifth, sixth and seventh input signals and calculate and generate a first output signal indicative of the amount of displacement  
15 of the linear or rotary drive means and a second output signal indicative of the direction of the displacement required to produce a negative or positive pumping pressure.

24. An apparatus as claimed in claim 23, wherein a negative pumping pressure draws the substance from the substance reservoir into the pump and a positive pumping pressure expels the substance from the pump to the conduit and so to the  
20 human or animal.

25. An apparatus as claimed in claim 24, wherein the first and second output signals are sent to a second control system adapted to convert them into third and fourth output signals indicative of drive means displacement and direction respectively, the third and fourth output signals being compatible with the linear or  
25 rotary drive means.

26. An apparatus as claimed in claim 25, wherein the input and output signals can be analog and/or digital.

27. A method of delivering a substance to a human or animal being supplied with breathable gas, the method including the steps of:

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measuring the pressure of the supplied breathable gas;  
detecting inhalation by the human or animal; and  
delivering the substance to the human or animal during inhalation at a pressure  
higher than the supplied pressure of the breathable gas.

5           28.     A method as claimed in claim 27, wherein the substance is a medicinal  
substance.

          29.     A method as claimed in claim 28, wherein the substance is in the form  
of a gas, mist, aerated suspension, jet, spray, gas mixture or the like.

          30.     A method as claimed in claim 27, wherein the substance is delivered  
10    to the respiratory system of the human or animal.

          31.     A method as claimed in claim 30, wherein the substance is delivered  
to the nasal airways of the human or animal.

          32.     A method as claimed in claim 27, wherein the supplied breathable gas  
is pressurised above atmospheric pressure.

15           33.     A method as claimed in claim 27, including the steps of measuring the  
volumetric flow rate of the breathable gas with an airflow sensor and generating a first  
input signal indicative of the breathable gas flow rate.

          34.     A method as claimed in claim 33, including the step of amplifying the  
first signal into a second signal also indicative of the breathable gas flow rate.

20           35.     A method as claimed in claim 33, including the step of differentiating  
the first signal into a third signal indicative of breathable gas acceleration or  
deceleration to indicate inhalation or exhalation respectively.

          36.     A method as claimed in claim 27, including the step of measuring the  
volume of the substance to be delivered to the human or animal.

25           37.     A method as claimed in claim 36, wherein the breathable gas pressure  
is measured with a pressure transducer adapted to generate a fourth input signal  
indicative of the breathable gas pressure.

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38. A method as claimed in claim 37, including the step of amplifying the fourth input signal into a fifth input signal also indicative of the breathable gas pressure.

39. A method as claimed in claim 27, wherein the substance is delivered  
5 to the human or animal using a positive displacement pump.

40. A method as claimed in any one of claim 39, wherein the positive displacement pump is a diaphragm pump.

41. A method as claimed in any one of claim 40, wherein the diaphragm pump is in fluid communication with a substance reservoir via a one-way valve adapted  
10 to allow the substance to only pass from the reservoir to the diaphragm pump.

42. A method as claimed in claim 40, wherein the diaphragm pump is also in fluid communication with the gas supply conduit via a one-way valve adapted to allow the substance to only pass from the diaphragm pump to the conduit.

43. A method as claimed in claim 40, wherein the diaphragm pump is  
15 displaced by a linear drive means.

44. A method as claimed in any one of claim 43, wherein the linear drive means is an electromagnet.

45. A method as claimed in claim 40, wherein the diaphragm pump is displaced by a rotary to linear converter driven by a rotary drive means.

46. A method as claimed in claim 45, wherein the rotary drive means is  
20 an electric DC motor, an electric AC motor, a stepper motor or a brushless motor.

47. A method as claimed in claim 43, further including the steps of inputting the second, third, fourth, fifth input signals and a predetermined sixth input signal indicative of the volume of the substance to be delivered and a predetermined  
25 seventh input signal indicative of the amount by which the pressure of the delivered substance should exceed the pressure of the breathable gas into a first control means and the first control system adapted to generating a first output signal indicative of the amount of displacement of the drive means and a second output signal indicative of the

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direction of the displacement required to produce negative or positive pumping pressure.

48. A method as claimed in claim 47, wherein a negative pumping pressure draws the substance from the substance reservoir into the pump and a positive  
5 pumping pressure expels the substance from the pump to the conduit and so to the human or animal.

49. A method as claimed in claim 48, further including the steps of inputting the first and second output signals into a second control system and the second control system adapted converting them into third and fourth output signals indicative  
10 of drive means displacement length and direction respectively, the third and fourth output signals being compatible with the linear or rotary drive means.

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# ABSTRACT

A substance delivery apparatus (10) for use with a system (12) for supplying breathable gas to a human or animal. The apparatus includes means (22) to measure the pressure of the supplied breathable gas means (22) to detect inhalation by the human  
6 or animal; and

means (54, 56, 58, 60) to deliver the substance (52) to the human or animal during inhalation at a pressure higher than the supplied pressure of the breathable gas.

A method of delivering a substance (52) is also disclosed.

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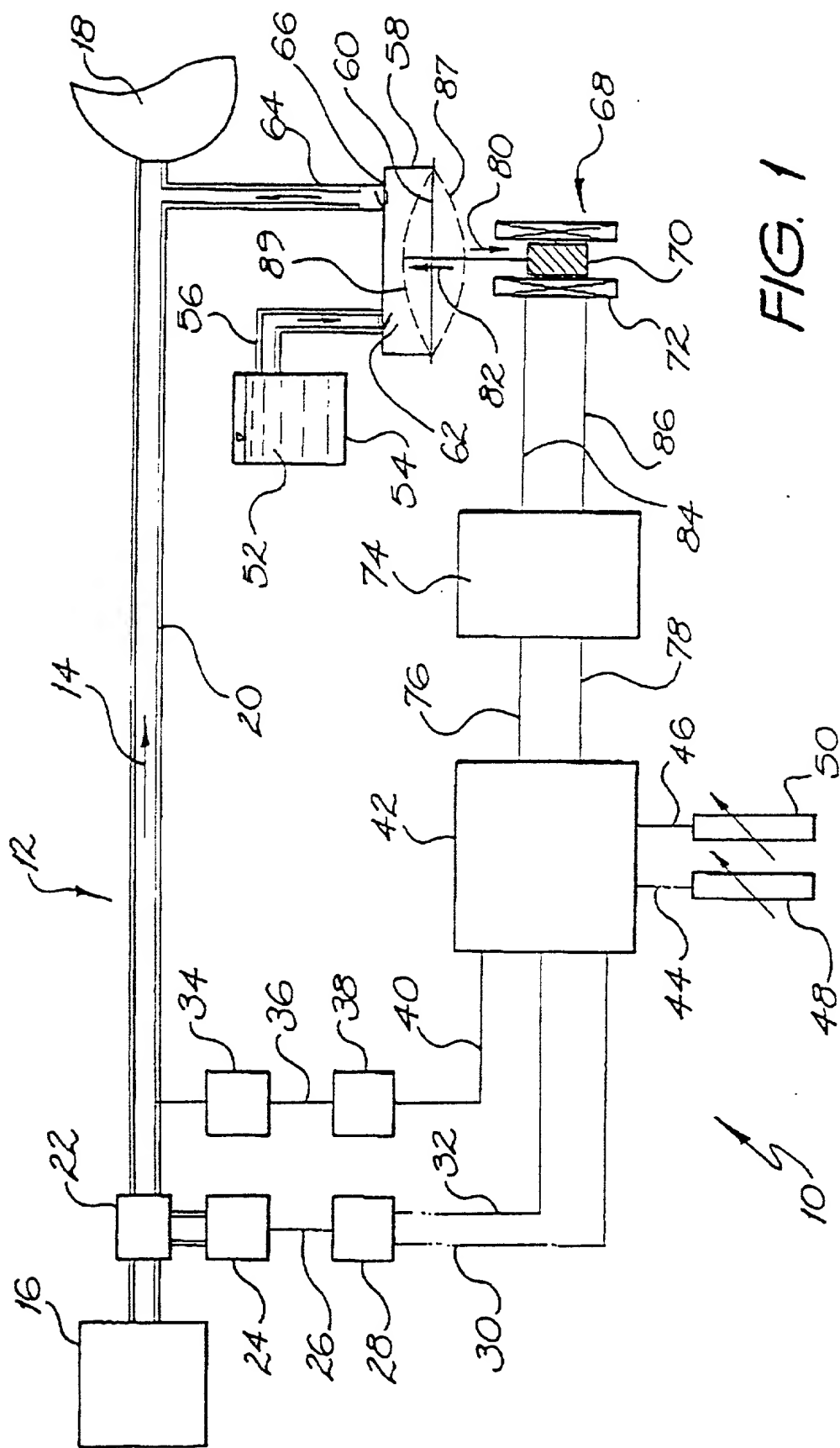


FIG. 1

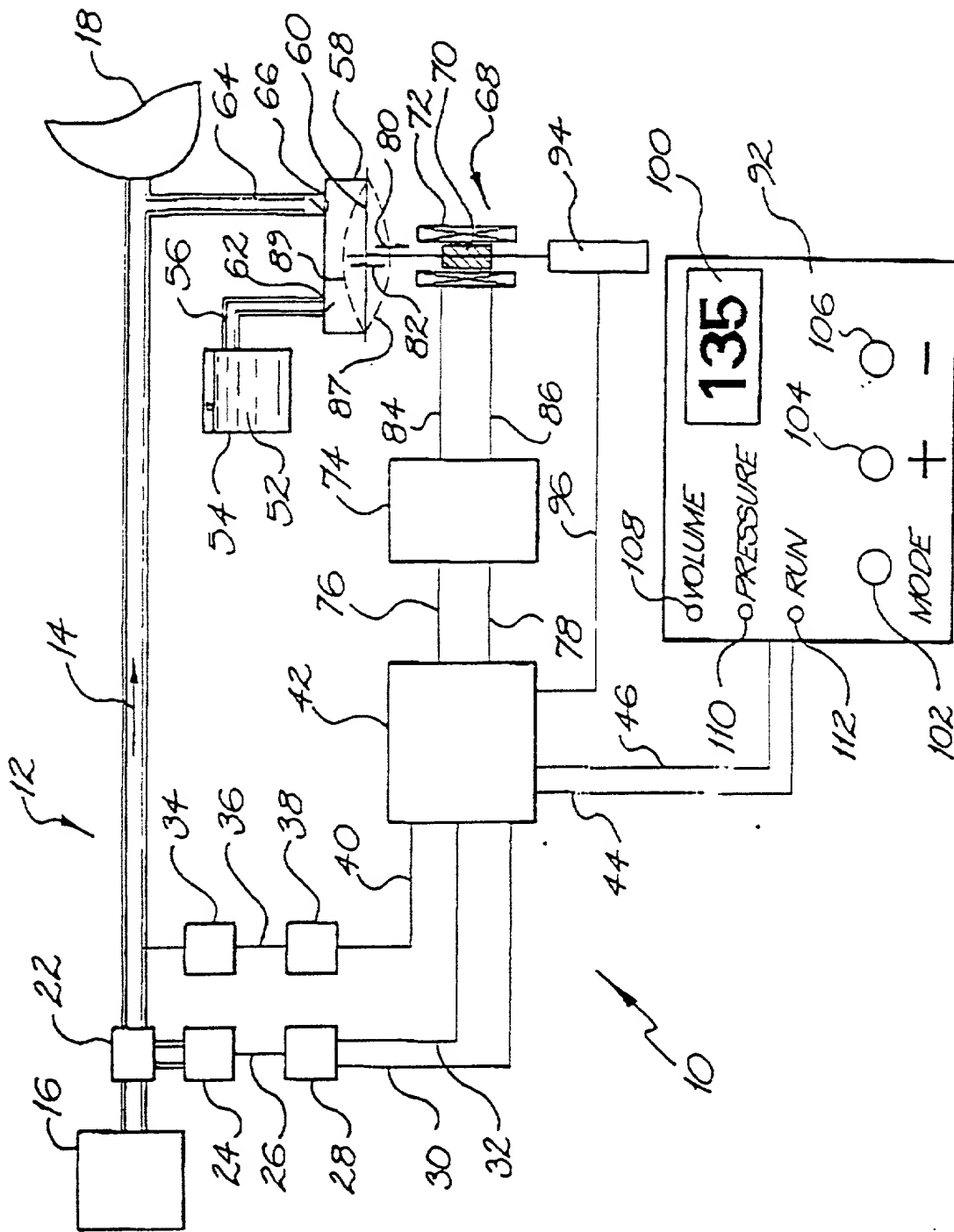


FIG. 2

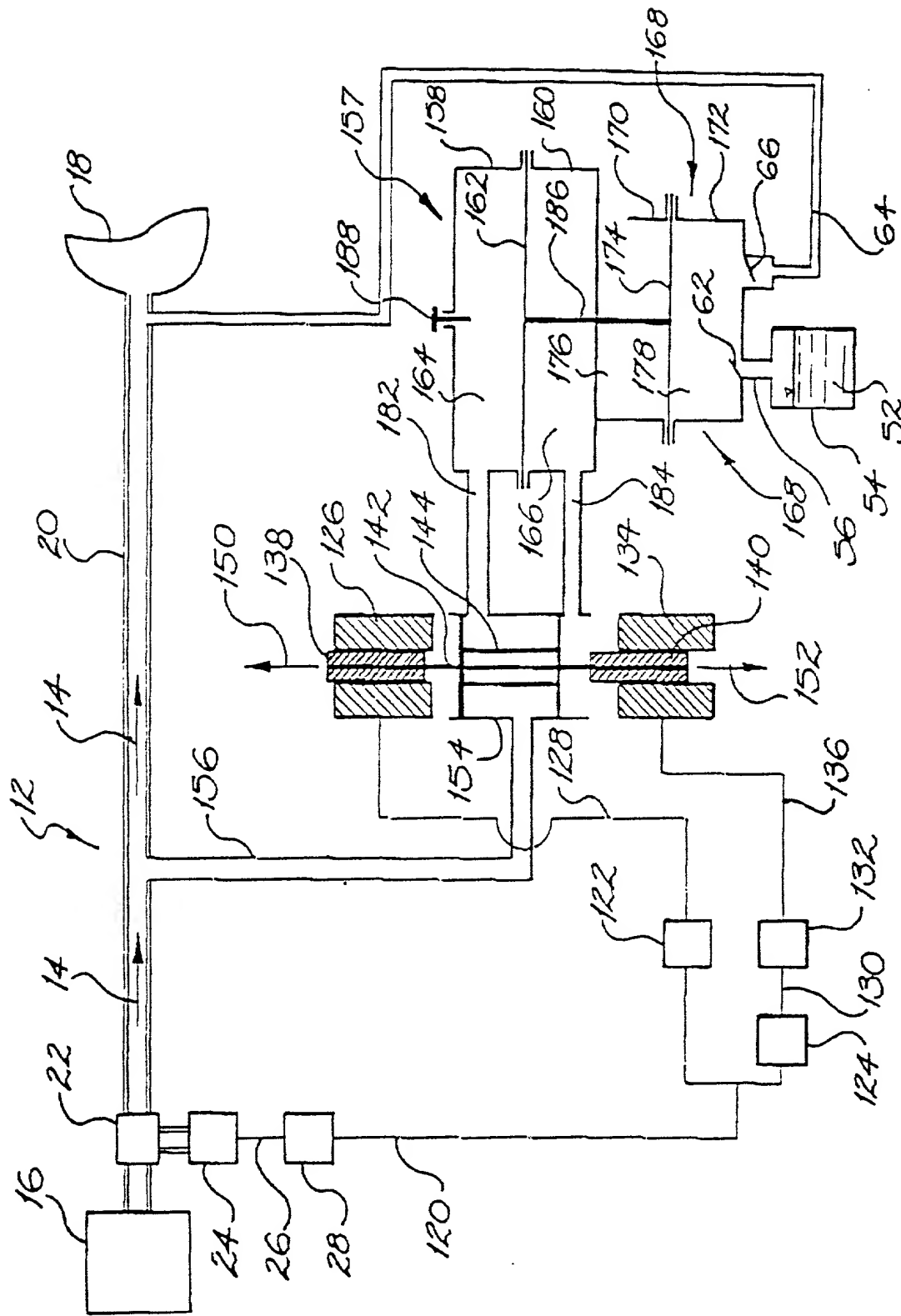


FIG. 3



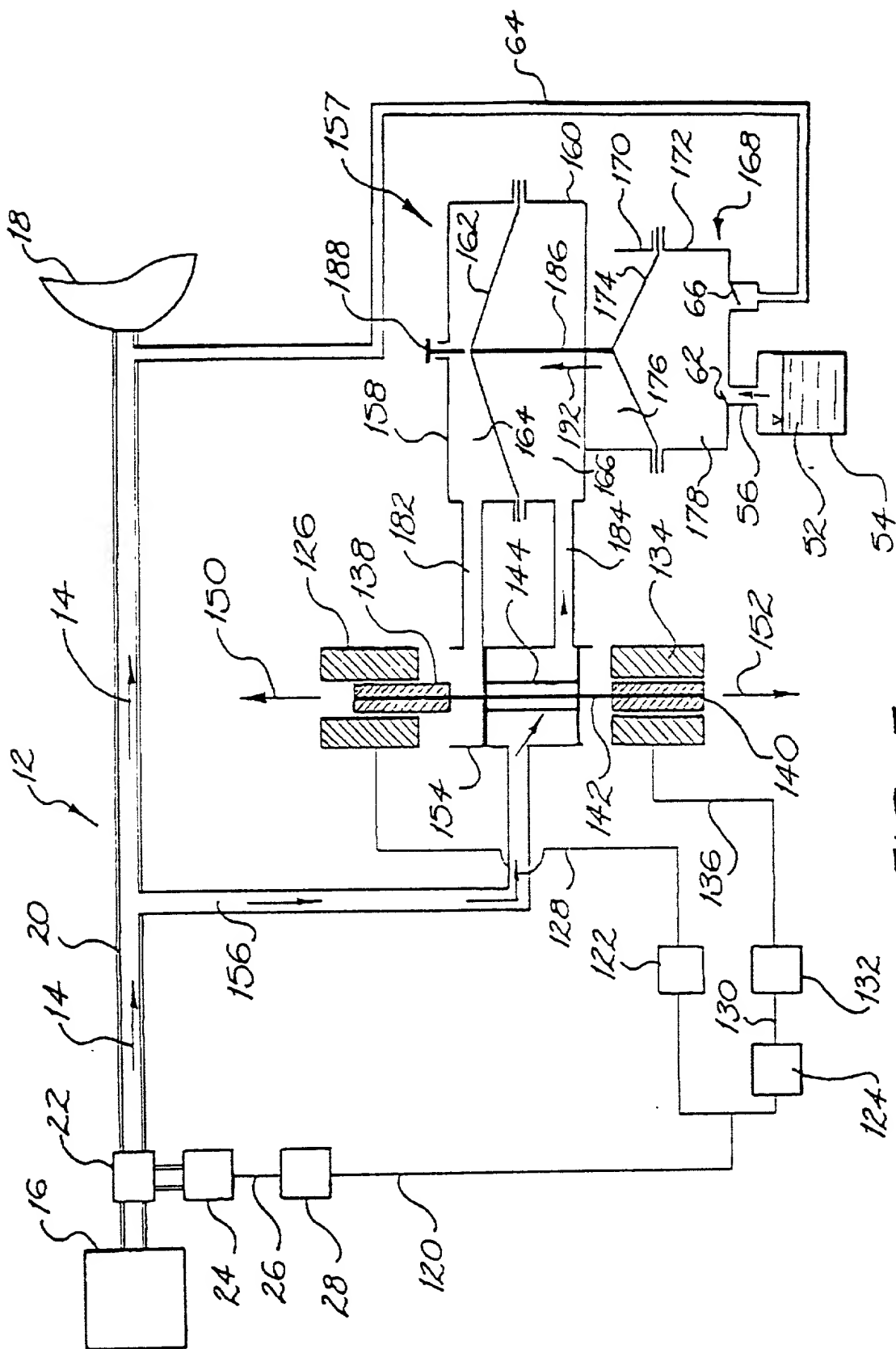


FIG. 5



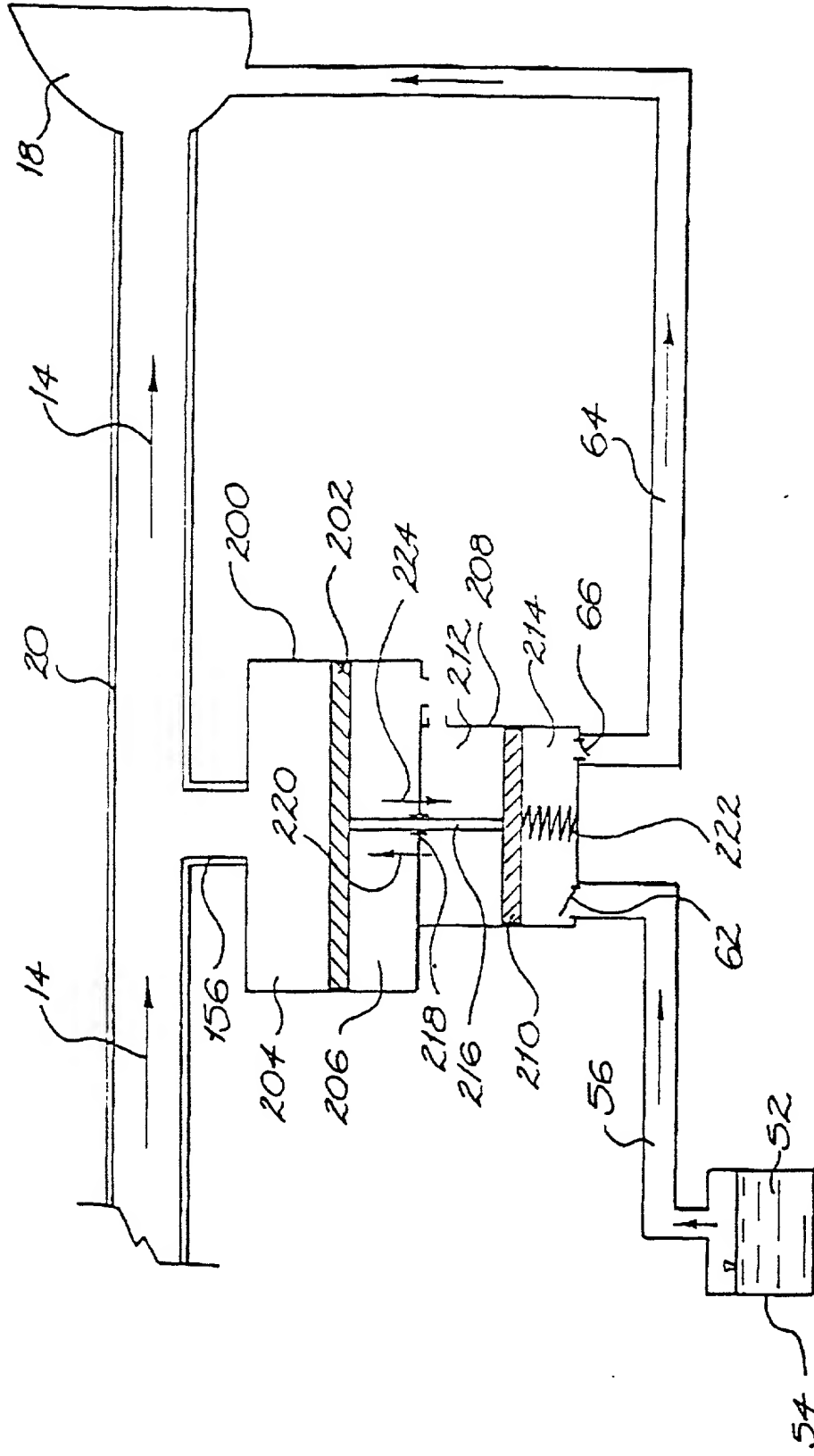


FIG. 6

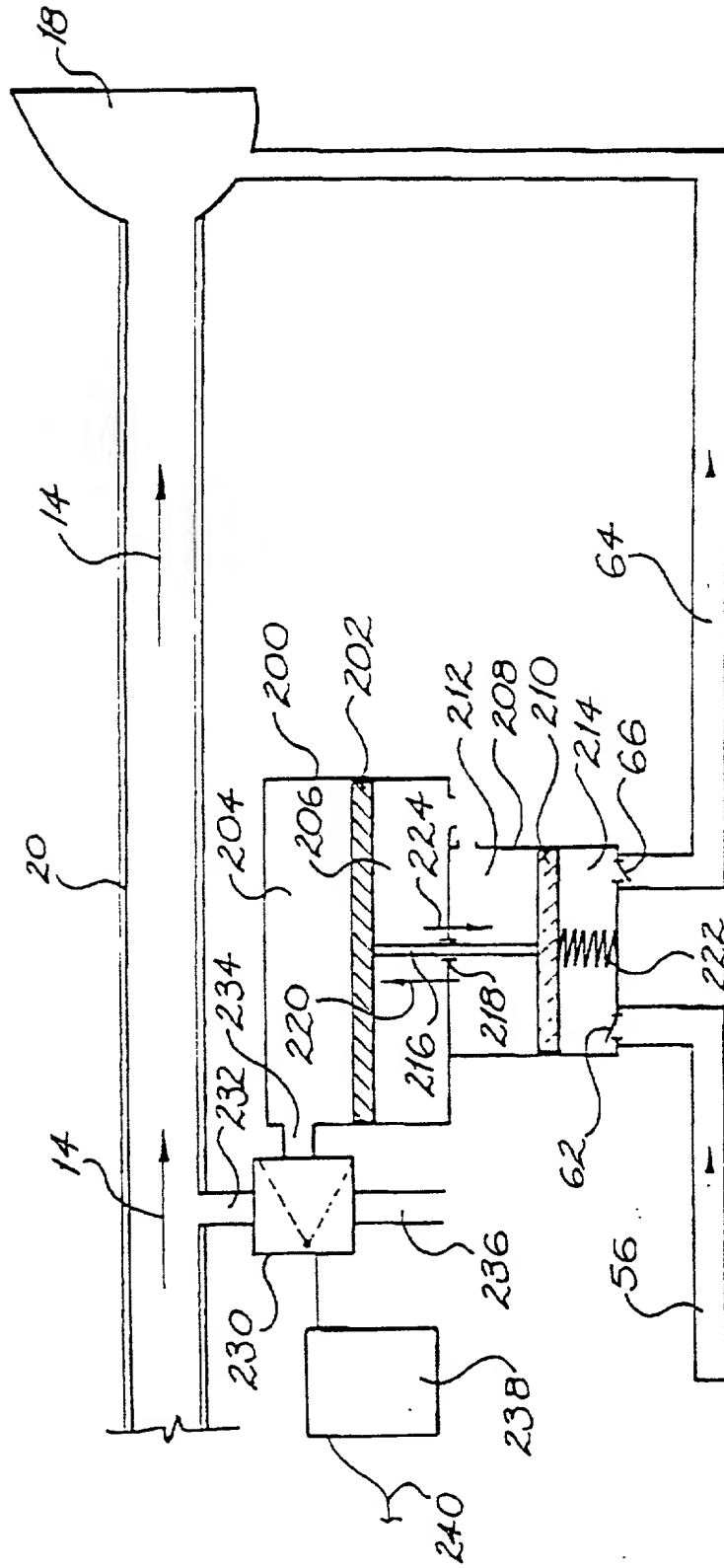


FIG. 7a

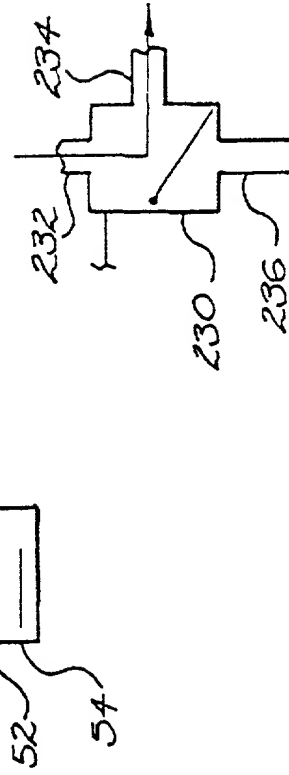


FIG. 7b

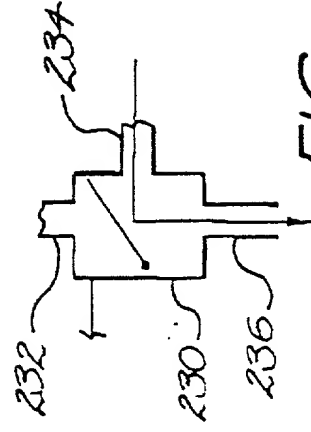


FIG. 7C

**COMBINED DECLARATION AND POWER  
OF ATTORNEY FOR PATENT APPLICATION**

**DECLARATION:**

As the below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled SUBSTANCE DELIVERY APPARATUS filed on \_\_\_\_\_, 1997, as Serial No. \_\_\_\_\_.

The person(s) named as inventor(s) in this application is Michel CALLAUD and Victor YERBURY

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a), as attached.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119/365 of any foreign application(s) for patent of inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed

- ☐ no such applications have been filed.  
☒ such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC § 119/365			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)
Australia	PO4186	12 December 1996	Pending
ALL FOREIGN APPLICATION(S), IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)

I hereby claim the benefit under Title 35, United States Code, § 120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. or PCT APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS (patented, pending, abandoned)

**POWER OF ATTORNEY:**

As a named inventor, I hereby appoint the following patent attorneys to prosecute this application and transact all business in the Patent Office connected therewith:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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§ 1.56 duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The office encourages applicants to carefully examine.

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
  - (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.
- (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
  - (i) Opposing an argument of unpatentability relied on by the Office, or
  - (ii) Asserting an argument of patentability.

A *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
  - (2) Each attorney or agent who prepares or prosecutes the application; and
  - (3) Each other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.
- (d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent or inventor.

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